

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Aurisicchio, et al.

Serial No. To Be Assigned

Filed: February 9, 2006

For: SYNTHETIC GENE ENCODING RHESUS MONKEY
CARCINOEMBRYONIC ANTIGEN AND USES
THEREOF

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

By Gabriel B. Crowley 2/9/06
MERCK & CO., INC.

10/568168

PATENT Case No. ITR0058YP

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Alysia A. Finnegan

Attorney / For Applicant(s)

Reg. No. 48,878

MERCK & CO., INC.

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(732)594-2583

Date: February 9, 2006

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				COMPLETE IF KNOWN	
				Application Number	To Be Assigned 111/268163
				Filing Date	February 9, 2006
				First Named Inventor	Aurisicchio, et al.
				Group Art Unit	
				Examiner Name	
Sheet	1	of	3	Attorney Docket Number	ITR0058P

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
		PCT	WO 01/24832		Pecher	04/12/2001
		PCT	WO 01/30382		Aventis Pasteur Limited	05/03/2001
		PCT	WO 02/022080		Merck & Co., Inc.	03/21/2002
		PCT	WO 02/38769		Muller	05/16/2002
		PCT	WO 03/018055		Merck	03/06/2003
		PCT	WO 03/059379		Pharmexa	07/24/2003
		PCT	WO 04/072287		Merck	
		PCT	WO 2004/092216		Trangene S.A.	10/28/2004
		PCT	WO 04/099247		Merck	
		EP	0 346 710		Miles, Inc.	06/03/1989

Examiner Signature		Date Considered	
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
			Application Number	To Be Assigned 10/568166	
			Filing Date	February 9, 2006	
			First Named Inventor	Aurisicchio, et al.	
			Group Art Unit		
			Examiner Name		
Sheet	2	of	3	Attorney Docket Number	ITR0058P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Andre, et al., "Increased Immune Response Elicited by DNA Vaccination with a Synthetic gp120 Sequence with Optimized Codon Usage", J. of Virol., Feb. 1998, Vol. 72, No. 2, pp. 1497-1503.
		Beauchemin, et al. "Isolation and Characterization of Full-Length Functional cDNA Clones for Human Carcinoembryonic Antigen", Molecular and Cellular Biology, Vol. 7, No. 9, pp. 3221-3230, Sept. 1987.
		Benchimol, et al., "Carcinoembryonic Antigen, a Human Tumor Marker, Functions as an Intercellular Adhesion Molecule", Cell, Vol. 57, pp. 327-334, April 21, 1989.
		Berinstein, et al., "Carcinoembryonic Antigen as a Target for Therapeutic Anticancer Vaccines: a Review", J. of Clinical Oncology, Vol. 20, No. 8, pp. 2197-2207, April 15, 2002.
		Chester, et al., "Recombinant anti-carcinoembryonic antigen antibodies for targeting cancer", Cancer Chemother. Pharmacol., Vol. 46 (Suppl) S8-S12, 2000.
		Facciabene, "Baculovirus Vectors Elicit Antigen-Specific Immune Responses in Mice", J. of Virol., Aug. 2004, Vol. 78, No. 16, pp. 8663-8672.
		Gold, et al., "Demonstration of Tumor-Specific Antigens in Human Colonic Carcinomata by Immunological Tolerance and Absorption Techniques", J. Exp. Med., Vol. 121, pp. 439-462 (1965).
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		Horig, et al., "Strategies for cancer therapy using carcinoembryonic antigen vaccines", Expert Reviews in Molecular Medicine Electronic Resource, Vol. 2000, pp. 1-24, 2000.
		Jantscheff, et al., "Search for CEA-Like Molecules In Polymorphonuclear leukocytes of non-human primates using monoclonal antibodies", Archiv. Fur Feschwulsforschung, Vol. 56, No. 2, 1986, pp. 113-6.
		Kantor, et al., "Immunogenicity and Safety of a Recombinant Vaccinia Virus Vaccine Expressing the Carcinoembryonic Antigen Gene in a Nonhuman Primate", Cancer Research, Vol. 52, pp. 6917-6925, 1992.
		Kim, et al., "Codon optimization for high-level expression of human erythropoietin (EPO) in mammalian cells", Gene, Vol. 191, pp. 293-301, 1997.
		Lathe, "Synthetic Oligonucleotide Probes Deduced from Amino Acid Sequence Data", J. Mol. Biol., Vol. 183, pp. 1-12, 1985.
		Montgomery, et al., "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors", DNA and Cell Biology, Vol. 12, No. 9, pp. 777-783, 1993.
		Paxton, et al., "Sequence Analysis of Carcinoembryonic Antigen: Identification of Glycosylation Sites and Homology With the Immunoglobulin Supergene Family", Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 920-924, February 1987.

Examiner Signature	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	To Be Assigned	
			Filing Date	February 9, 2006	
			First Named Inventor	Auriscchio, et al.	
			Group Art Unit		
			Examiner Name		
Sheet	3	of	3	Attorney Docket Number	ITR0058P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Scholl, et al., "Gene Therapy Applications to Cancer Treatment", J. of Biomedicine and Biotechnology", 2003:1, pp. 35-47, 2003.
		Screaton, et al., "Carcinoembryonic Antigen, A Human Tumor Marker, Cooperates with Myc and Bcl-2 in Cellular Transformation", J. of Cell Biology, Vol. 137, No. 4, pp. 939-952, May 19, 1997.
		Shiver, et al., "Cytotoxic T Lymphocyte and Helper T Cell Responses following HIV Polynucleotide Vaccination", Annals. New York Academy of Sciences, Vol. 772, pp. 198-208, 1995.
		Taheri, et al., "Self Recognition in the Ig Superfamily", J. of Biol. Chem., Vol. 275, No. 35, Sept. 2000, pp. 26935-26943.
		Thompson, et al., "Molecular cloning of a gene belonging to the carcinoembryonic antigen gene family and discussion of a domain model", Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 2965-2969, May 1987.
		Wheeler, et al., "Safety and Immunogenicity of a recombinant vaccinia virus vaccine expressing a 70kDa fragment of the human carcinoembryonic antigen in a nonhuman primate", Proceedings of the American Association for Cancer Research", Vol. 36, March 1995, pp. 366.
		Virji, et al., "CEA and innate immunity", TRENDS in Microbiology, Vol. 9, No. 6, June 2001, pp. 258-259.

Examiner Signature		Date Considered	
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